

Opening Statement of Honorable Michael C. Burgess, M.D.
Subcommittee on Health Hearing
“Examining Improvements to the Regulation of Medical
Technologies”
May 1, 2017

(As prepared for delivery)

Today’s hearing is another step in this subcommittee’s work to reauthorize the Food and Drug Administrations’ user fee agreements with industry. The subcommittee has held three hearings on the user fee program, during which time members examined proposed agreements for generic drugs, biosimilar products, branded drugs, and medical devices. Last month, bipartisan leaders of the Senate and House committees on health released a discussion draft to reauthorize those agreements. Today we will consider several bipartisan bills intended to further improve the regulation of medical technologies. It is my top priority to build upon this committee’s work in the 21st Century Cures Act to get safe and effective treatments to patients and providers without unnecessary delay.

H.R. 1652, the Over-the-Counter Hearing Aid Act of 2017, would implement recommendations from the President’s Council of Advisors on Science and Technology, and the National Academies of Science Engineering and Medicine. Specifically, H.R. 1652 would direct FDA to promulgate regulations establishing a category for over-the-counter hearing aids. This category of OTC hearing aids would be limited to use by adults with mild to moderate hearing loss. Representatives Kennedy, Blackburn, and Carter introduced this bill to safely increase access and affordability in the hearing aid market for the millions of Americans that could benefit from it.

Representatives Costello and Peters introduced H.R. 2009, the Fostering Innovation in Medical Imaging Act of 2017. This bill seeks to improve the regulation and oversight of medical imaging devices intended for used in conjunction with contrast agents. H.R. 2009 takes targeted steps to reduce excessive regulatory burdens so that patients and physicians have access to a robust market of medical imaging technologies.

H.R. 2118, the Medical Device Servicing and Accountability Act, also introduced by Representatives Costello and Peters, would require all medical device servicers to register with the FDA and maintain a complaint handling system—currently,

only original equipment manufacturers are required to register and report. This bill seeks to increase visibility and accountability for all parties servicing medical devices in order to ensure that devices used for patient care continue to perform safely and effectively.

Representatives Bucshon, Peters, Brooks, and Butterfield introduced the fourth bill we will consider today, H.R. 1736. This bill would modernize FDA's device inspections process to increase its consistency and transparency. More specifically, H.R. 1736 would establish a risk-based inspections schedule for device facilities, standardize inspection processes, and increase transparency around FDA determinations related to inspections.

Each of the bills we will examine today is intended to increase innovation and access to medical devices and technology by making certain that the regulatory environment is consistent, effective, and agile. Ensuring that patients and providers continue to benefit from safe and innovative medical technology is a shared priority in our work to reauthorize the FDA user fee programs. I thank all of our witnesses for being here, and I look forward to hearing from each of you about how these proposals might improve our ability to meet this goal.